

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addease COMMISSIONER FOR PATENTS PO Box 1430 Alexandra, Virginia 22313-1450 www.webjo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/509,743	09/30/2004	Kazuo Miyazawa	0038-0447PUS1	4365	
2292 7590 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAM	EXAMINER	
			NGUYEN, PHONG H		
			ART UNIT	PAPER NUMBER	
			3724		
			NOTIFICATION DATE	DELIVERY MODE	
			05/30/2008	ELECTRONIC	

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail  $\,$  address(es):

mailroom@bskb.com

## Application No. Applicant(s) 10/509 743 MIYAZAWA ET AL. Office Action Summary Examiner Art Unit PHONG H. NGUYEN 3724 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 31 March 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) 2.4.11 and 13 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1,3,5-10,12 and 14-20 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 30 September 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_\_

Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

Application/Control Number: 10/509,743 Page 2

Art Unit: 3724

### DETAILED ACTION

### Specification

The Specification is objected to under 37 CFR 1.71 because it does not describe a
means for adjusting the shortest distance between the close roller and a slice starting
point in claim 20.

### Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a means for adjusting the distance between the close roller and the slice starting point must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application

must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abevance.

## Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20 calls for a means for adjusting a shortest distance between the close roller and the slice starting point. There are numerous ways to adjust the shortest distance between the close roller and a slice starting point and the applicant has not set forth any specific way. Therefore, it is unclear what kind of adjusting means for the close roller that the applicant had possession at the time the application was filed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5-10, 12 and 14-20 are rejected under 35 U.S.C. 112, second
paragraph, as being indefinite for failing to particularly point out and distinctly claim the
subject matter which applicant regards as the invention.

Claims 1, 10, 19 and 20 recite the limitation "the tissue section" in the body of the claims. There is insufficient antecedent basis for this limitation in the claim. The phrase "to form a tissue section" should be likely added after the term "a slicing surface" in the second paragraph of the claims to set up antecedent basis for the limitation "the tissue section".

Claim 20 calls for means for adjusting the shortest distance between the close roller and a slice starting point. There is an indefinite number of ways to do that and the specification does not set forth any specific way to perform that function.

### Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
  obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1, 3, 7, 8, 10, 12, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickett (3,733,948), hereinafter Pickett 948, in view of Pickett (3,552,247), hereinafter Pickett 247.

Regarding claim 1, Pickett 948 teaches a method for manufacturing a tissue section, which is used for a sample for observation by a microscope, comprises the steps of:

slicing an organism specimen (mounted on the specimen holder 12 in Fig. 1) along a slicing surface (defined by surface of the cutting blade 80 in Fig. 13) in an atmosphere of air, a form of the organism specimen having been fixed by freezing or by using an embedding agent (it is well known that specimens are frozen or embedded in paraffin before the slicing process occurs. See Background technology section in the applicant's disclosure.);

adjusting a distance between the slicing surface of the organism specimen and one side of a film 180 (as shown in Figs. 13 and 14, the clamping force changes the shape of the blade 80 which is the slicing surface; and the distance between the slicing surface and the film 180 are changed accordingly. Therefore, the distance between the sliding surface and the film is considered to be adjustable.) when the slicing of the organism specimen is started, thereby a tip part of the tissue section curling to the outside of the slicing surface of the organism specimen is allowed to adhesively abut on one side of the film running apart from the slicing surface of the organism specimen (it is to be noted that the curly part of the specimen abuts the film after being straighten out in the trough.); and

running the film at a speed in synchronism with a slicing speed of the tissue section after the tip part of the tissue section is allowed to adhesively abut on the one side

of the film, thereby the entire tissue section cut off from the organism specimen can be adhered onto the one side of the film.

Pickett 948 does not teach adjusting a temperature difference between the organism specimen and the film when the slicing of the organism specimen is started, thereby a tip part of the tissue section curling to the outside of the slicing surface of the organism specimen is allowed to adhesively abut on one side of the film running apart from the slicing surface of the organism specimen.

Pickett 247 teaches heating and keeping the water in a trough 20 (Figs. 2-4) at 52° C and a slicing blade at 35° C which is equivalent to a trough 185 in Pickett 948 for preventing curly portions on a cut specimen when the cut specimen adhesively abuts on a film. The temperature of the portion of a film 70 in the trough 20 is raised from the room temperature to 52° C due to the raising temperature of the water and the temperature of the specimen is raised from the room temperature to 52° C (if the specimen is embedded in paraffin) or freezing temperature (if the specimen is in frozen form), therefore, the temperature of the film and the specimen is considered to be adjusted for preventing curly portions on a cut specimen.

Therefore, it would have been obvious to one skill in the art at the time the invention was made to adjust the temperature of the film and the specimen by heating and keeping the water in the trough 185 at 52° C and a slicing blade 80 at 35° C for preventing curly portions on a cut specimen when the cut specimen adhesively abuts on a film

Regarding claim 10, Pickett 948 teaches a device for manufacturing a tissue section, which is used for a sample for observation by a microscope, comprises the steps of:

Page 7

means 80 (Fig. 13) for slicing an organism specimen (mounted on the specimen holder 12 in Fig. 1) along a slicing surface (defined by surface of the cutting blade 80 in Fig. 13) in an atmosphere of air, a form of the organism specimen having been fixed by freezing or by using an embedding agent (it is well known that specimens are frozen or embedded in paraffin before the slicing process occurs. See Background technology section in the applicant's disclosure);

means for running a film a part from the slicing surface of the organism specimen (a motor means inherently in the microtome for moving a section of the film to and away from the slicing surface);

means 65 for adjusting a distance between the slicing surface of the organism specimen and one side of a film 180 (as shown in Figs. 13 and 14, the clamping force of element 65 changes the shape of the blade 80 which is the slicing surface; and the distance between the slicing surface and the film 180 are changed accordingly.

Therefore, the distance between the sliding surface and the film is considered to be adjustable) when the slicing of the organism specimen is started, thereby a tip part of the tissue section curling to the outside of the slicing surface of the organism specimen is allowed to adhesively abut on one side of the film running apart from the slicing surface

of the organism specimen (it is to be noted that the curly part of the specimen abuts the film after being straighten out in the trough.).

Pickett 948 does not teach (1) means for adjusting a temperature difference between the organism specimen and the film when the slicing of the organism specimen is started, thereby a tip part of the tissue section curling to the outside of the slicing surface of the organism specimen is allowed to adhesively abut on one side of the film running apart from the slicing surface of the organism specimen, (2) means for synchronizing a slicing speed of the tissue section, whose tip part has been adhered on the one side of the film, and a running speed of the film so as to adhere the entire tissue section cut off from the organism specimen onto the one side of film.

Pickett 247 teaches a thermoelectric unit 99 for heating and keeping the water in a trough 20 (Figs. 2-4) at 52° C and a slicing blade at 35° C which is equivalent to a trough 185 in Pickett 948 for preventing curly portions on a cut specimen when the cut specimen adhesively abuts on a film. The temperature of the portion of a film 70 in the trough 20 is raised from the room temperature to 52° C due to the raising temperature of the water and the temperature of the specimen is raised from the room temperature to 52° C (if the specimen is embedded in paraffin) or freezing temperature (if the specimen is in frozen form), therefore, the temperature of the film and the specimen is considered to be adjusted for preventing curly portions on a cut specimen.

Therefore, it would have been obvious to one skill in the art at the time the invention was made to incorporate a thermoelectric unit as taught by Pickett 247 to the

microtome of Pickett 948 to adjust the temperature of the film and the specimen by heating and keeping the water in the trough 185 at 52° C and a slicing blade 80 at 35° C for preventing curly portions on a cut specimen when the cut specimen adhesively abuts on a film

Pickett 247 teaches a means (16, 55 & 56) for synchronizing a slicing speed of the tissue section, whose tip part has been adhered on the one side of the film, and a running speed of the film so as to adhere the entire tissue section cut off from the organism specimen onto the one side of film. See Fig. 1.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to incorporate the synchronizing means as taught by Pickett 247 to the microtome of Pickett 948 for synchronizing the slicing speed and the transferring speed of the film.

Regarding claim 3, at 52° C the frozen specimen is melted.

Regarding claim 7, Pickett 948 teaches the invention substantially as claimed except for the film running speed is adjusted so as not to form creases in the tissue section and break the tissue section.

Pickett 247 teaches the film running speed is adjusted so as not to form creases in the tissue section and break the tissue section. See col. 3, line 70-col.4, line 7. It is to be noted that if the film does not have a sufficient speed, the second tissue hits the first tissue and creates creases.

Application/Control Number: 10/509,743

Art Unit: 3724

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to include the film speed controlling device as taught by Pickett 247 to the method of Pickett 948 to prevent forming of creases on the tissue.

Regarding claims 8 and 17, at least the ratio of the film running speed and the slicing speed is 1 which is within the claimed range of 1.2-0.8 since the second cut specimen does not hit the first cut specimen when the first cut specimen is still in the trough.

Regarding claim 12, Pickett 948 teaches the invention substantially as claimed except for the temperature adjusting means for adjusting the temperature of the film.

Pickett 247 teaches a temperature adjusting means 99 for raising water temperature in the trough to 52° C, which also results in raising the temperature of the portion of the film in the trough to 52° C so that the tissue section is flatly adhered to the film.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to incorporate the temperature adjusting means as taught by Pickett 247 to the microtome of Pickett 948 so that the tissue portion can be flatly adhered to the film.

Regarding claim 16, Pickett 948 teaches the invention substantially as claimed except for the film running speed is adjusted by a control means so as not to form creases in the tissue section and break the tissue section.

Pickett 247 teaches the film running speed is adjusted by a control means (16, 55 & 56) so as not to form creases in the tissue section and break the tissue section. See col. 3, line 70-col.4, line 7. It is to be noted that if the film does not have a sufficient speed, the second tissue hits the first tissue and creates creases.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to include the control means as taught by Pickett 247 to the microtome of Pickett 948 to prevent forming of creases on the tissue.

 Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickett (3,733,948), hereinafter Pickett 948, in view of Pickett (3,552,247), hereinafter Pickett 247 as applied to claims1 and 10 above, and further in view of Ullberg (3,690,988).

Regarding claim 9, the modified specimen slicing method of Picket 948 teaches the invention substantially as claimed except for if the film is transparent.

Ullberg teaches that it is well known in the art to use a transparent film for conveying tissues. See col. 4, lines 50-55.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to use a transparent film as taught by Ullberg in the specimen slicing method of Pickett 948 for conveying tissues.

Regarding claim 9, the microtome of Picket 948 teaches the invention substantially as claimed except for if the film is transparent. Ullberg teaches that it is well known in the art to use a transparent film for conveying tissues. See col. 4, lines 50-55.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to use a transparent film as taught by Ullberg in the microtome of Pickett 948 for conveying tissues.

### Allowable Subject Matter

Claim 19 is allowed.

The following is a statement of reasons for the indication of allowable subject matter: claim 19 is allowable for setting forth the close roller moving to a slice starting point, guiding a film running apart from a guiding surface and allowing the tip part of the tissue to contact the film

Claim 20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1st and 2nd paragraphs, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: claim 20 is allowable for setting forth the close roller moving to a slice starting point, guiding a film running apart from a guiding surface and allowing the tip part of the tissue to contact the film.

11. Claims 5, 6, 14 and 15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: claims 5 and 14 are allowable for setting forth the close roller moving to and away from the slicing surface.

#### Response to Arguments

 Applicant's arguments with respect to claims 1, 3, 5-12, 14-18 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHONG H. NGUYEN whose telephone number is (571)272-4510. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Boyer Ashley can be reached on 571-272-4502. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. H. N./ Examiner, Art Unit 3724 May 19, 2008